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Governor

Judith A. Monroe, M.D.
State Health Commissioner




Indiana State Department of Health

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DATE: October 19, 2009

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: 
A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

SUBJECT: FDA NEWS RELEASE

SUGGESTED

ACTION: None; Information provided in case of consumer inquiry.

FDA NEWS RELEASE

For Immediate Release: Oct. 19, 2009
Media Inquiries: Christopher Kelly, 301-796-4676, christopher.kelly@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA, FTC Issue Joint Warning Letter to Web Site Offering Fraudulent H1N1 Flu Supplements

Agencies continue effort to protect public health from illegal Web activity

On October 15, 2009, the U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) issued a joint warning letter to a Web site marketing fraudulent supplements that claim to help prevent the spread of the 2009 H1N1 influenza virus.

The warning letter, the first to be issued jointly by the agencies, advises the owners of the site that they must discontinue the fraudulent marketing of their product or face legal action. The letter further advises the owners of the site that they have 48 hours to give the agencies a plan to discontinue their fraudulent marketing.

The FDA and the FTC remind consumers to be cautious of promotions or Internet sites offering products for sale that claim to diagnose, prevent, mitigate, treat or cure the 2009 H1N1 influenza virus. Fraudulent H1N1 influenza products come in many varieties, including dietary supplements, as well as products purporting to be drugs, medical

devices or vaccines. Since May 2009, the FDA has warned more than 75 Web sites to stop the sale of more than 135 products with fraudulent H1N1 influenza virus claims.

“Products that are offered for sale with claims to diagnose, prevent, mitigate, treat or cure the 2009 H1N1 influenza virus must be carefully evaluated,” said Commissioner of Food and Drugs Margaret A. Hamburg, M.D. “Unless these products are proven to be safe and effective for the claims that are made, it is not known whether they will prevent the transmission of the virus or offer effective remedies against infection. Furthermore, they can make matters worse by providing consumers with a false sense of protection.”

The FDA and the FTC also warn consumers to take extreme care when buying products over the Internet that claim to diagnose, prevent, treat or cure the H1N1 influenza virus because, in addition to being fraudulent, they could be dangerous.

In collaboration with the FTC, the FDA will continue to work aggressively to identify, investigate and take regulatory action against individuals or businesses that wrongfully promote purported 2009 H1N1 influenza products.

This will include taking joint action, when appropriate, such as the issuance of last Thursday's warning letter. Additional legal action could include an injunction or issuance of an administrative order by the FTC or seizure of products, an injunction or criminal prosecution by the FDA.

“The FDA continues to consider the sale and promotion of fraudulent H1N1 influenza products to be a possible threat to the public health and in violation of the Federal Food Drug and Cosmetic Act,” said Michael Chappell, acting associate commissioner for regulatory affairs. “The FDA has an aggressive surveillance program to detect fraudulent H1N1-related products and will take prompt action to stop the marketing of fraudulent H1N1 influenza products and will hold those who are responsible for doing so accountable.”

To view the warning letters, visit:

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/default.htm>.

There are two antiviral drugs approved by the FDA for treatment and prophylaxis of the 2009 H1N1 influenza virus – Tamiflu (oseltamivir phosphate) and Relenza (zanamivir). Tamiflu and Relenza, in addition to their approved labeling, have been issued Emergency Use Authorizations by the FDA that describe specific authorized uses during this public health emergency.

H1N1 Flu Fraud Widget

This week, the FDA enhanced its efforts to warn the public about potentially deceptive H1N1 influenza products and to report suspected criminal activity with the release of an H1N1 flu fraud widget.

The portable application, embedded in a Web page that can be copied onto any other Web site or blog, will allow the public to play an active role in preventing flu fraud, and is available at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm186340.htm>

Consumers are urged to report any suspected fraudulent products or criminal activity relating to FDA-regulated products associated with H1N1 influenza virus, including the names of Web sites that may be offering these products for sale, to the FDA by visiting: <http://www.accessdata.fda.gov/scripts/email/oc/oci/flucontact.cfm>

Consumers are urged to purchase and consume only FDA-approved or authorized medical products to diagnose, treat, prevent, or cure infections caused by the H1N1 virus. Consumers also are urged to contact their health care provider if they have any questions or concerns about medical products or personal protective equipment.

For more information:

FDA 2009 H1N1 (Swine) Flu Page

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm>

Centers for Disease Control and Prevention – 2009 H1N1 Flu (Swine Flu)

<http://www.cdc.gov/h1n1flu/>

Fraudulent 2009 H1N1 Influenza Products List

<http://www.accessdata.fda.gov/scripts/h1n1flu/>

Influenza Antiviral Drugs and Related Information

<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm>

The Federal Government's Influenza Web site

<http://www.flu.gov/>

FTC Warns Internet Peddlers that Potentially Bogus H1N1 Influenza Products May Violate Federal Law—Press Release, May 5, 2009

<http://www2.ftc.gov/opa/2009/05/swineflu2.shtm>